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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,582	10/31/2003	Meir Stern	85189-5300	1887

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WINSTON & STRAWN LLP
PATENT DEPARTMENT
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,582	STERN ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-38,40-48,50 and 53-79* is/are pending in the application.

4a) Of the above claim(s) *40-48,50,53-55 and 57-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-38 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 26, 2007 has been entered.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The declaration under 37 CFR 1.132 filed February 26, 2007 is sufficient to overcome the rejection of claims 22-25, 37 under 35 U.S.C. 102(b) based upon Haralambopoulos (US 5958447).

Claims 1-21, 39, 49, 51-52 are canceled. Claims 40-48, 50, 53-55, 57-79 are withdrawn. Claims 22-38, 56 are currently under examination.

Priority: The priority date is October 31, 2002.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-25, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447; previously cited) in view of Hoeck et al. (US 6335030). Haralambopoulos teaches a transdermal patch comprising a bioactive substance can be formulated as a powder, liquid, or semi-liquid, e.g. gel or emulsion, and applied between the adhesive surface of a tape and its release liner (or its backing layer, for a transfer tape) (col. 3, lines 5-20). In Figure 1, Haralambopoulos teaches an active substance (or mixture of substances) in powder form is sprinkled, deposited, or spread uniformly as a thin layer on an exposed adhesive surface of a patch of a prefabricated pressure sensitive adhesive tape, which is comprised of a backing layer and a pressure sensitive adhesive matrix (col. 6 lines 45-50; claims 22-25). Haralambopoulos teaches the incorporation of powdered ascorbic acid into a transdermal patch (col. 8 lines 6-9; lines 22-25). Haralambopoulos does not teach a non-adhesive liner.

Hoeck et al. disclose transdermal patches can be categorized into four main groups, including the matrix type, in which the drug is placed within a non-adhesive polymeric material, and sandwiched between an adhesive/liner overlay layer a backing layer (col. 4 lines 37-39, Fig. 1A).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Haralambopoulos by depositing a bioactive substance in dried form on the non-adhesive polymeric material of the transdermal patch of Hoeck et al. instead of the adhesive surface of the transdermal patch of Haralambopoulos (claims 22-25, 37). One of ordinary skill would be motivated to formulate a transdermal patch by depositing a dried

bioactive substance on the non-adhesive polymeric layer of a matrix type transdermal patch and expect to acquire a successful product because Hoeck et al. disclose different types of transdermal patches have the same ultimate purpose, which is to deliver a drug by transdermal means.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447; previously cited) in view of Hoeck et al. (US 6335030). The teachings of Haralambopoulos are outlined above. In column 6, line 47, Haralambopoulos discloses an active substance (or mixture of substances) in powder form can be sprinkled or spread uniformly as a thin layer on an exposed surface adhesive surface of a patch. Additionally, Haralambopoulos teaches ascorbic acid can be combined and formulated with additional carriers, i.e. glycerin, propylene glycol, polypropylene glycol, polyethylene glycol, ethanol, lanolin, and mineral oils (col. 12 line 30). Haralambopoulos does not teach a non-adhesive liner.

Hoeck et al. disclose transdermal patches can be categorized into four main groups, including the matrix type, in which the drug is placed within a non-adhesive polymeric material (col. 4 lines 37-39, Fig. 1A).

In view of modern pharmaceutical practice, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a buffering agent or a preservative into a mixture of substances, including a bioactive substance, in powder form into the transdermal patch of Haralambopoulos in view of Hoeck et al. because Haralambopoulos discloses a bioactive substance and/or a mixture of substances can be successfully incorporated into a transdermal patch (claim 38).

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447; previously cited) in view of Hoeck et al. (US 6335030). The teachings of Haralambopoulos are outlined above. Haralambopoulos does not teach two electrodes integrated into the patch.

The teachings of Hoeck et al. are outlined above. Hoeck et al. further disclose an iontophoretic type transdermal patch (col. 4 lines 48-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to integrate electrodes into the transdermal patch of Haralambopoulos in view of Hoeck et al. because Hoeck et al. discloses that an electrical potential gradient can be used in a transdermal patch for delivering drug through the skin (claim 56). One of ordinary skill would be motivated to integrate at least two electrodes into the patch of Haralambopoulos in view of Hoeck et al. because more electrodes will allow more electricity to be supplied to the skin; therefore, allowing better penetration of the skin barrier and more efficient delivery of the drug and/or medication.

Claims 26, 28-29, 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447; previously cited) in view of Hoeck et al. (US 6335030) in view of Sintov et al. (US 6274166; previously cited). The teachings of Haralambopoulos are outlined above.

The teachings of Hoeck et al. are also outlined above. Neither Haralambopoulos nor Hoeck et al. teach insulin as an active agent.

Sintov et al. teach a transdermal delivery system comprising an active ingredient selected from the group consisting of peptides, proteins, and mixtures thereof. Topical proteins such as insulin can be incorporated into pharmaceutically acceptable carriers such as gels, ointments, solutions, paste, powder, and an adhesive patch (col. 3 lines 53-56). Further, Sintov et al. disclose the therapeutic proteins and its protectors/stabilizers can be applied as a topical formulation such as a cream, ointment, or gel (col. 4 lines 43-45). Sintov et al. disclose a transdermal patch can consist of several layers including the drug layer containing the adhesive polymer, plasticizer, oxidizing agents, penetration enhancers and other excipients (col. 4 lines 50-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising insulin with additional agents such as stabilizers and/or polymers into the transdermal patch of Haralambopoulos in view of Hoeck et al. because Sintov et al. teach proteins such as insulin can be incorporated into pharmaceutically acceptable carriers and stabilizers in the form of a powder for topical delivery and Haralambopoulos in view of Hoeck et al. teach powdered bioactive substances can be spread uniformly as a thin layer on an non-adhesive polymeric layer of a matrix type transdermal patch (claims 26, 28-29, 32-33).

Claims 27, 29, 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447; previously cited) in view of Hoeck et al. (US 6335030) in view of Marin (US 6274582; previously cited). The teachings of Haralambopoulos are outlined above.

The teachings of Hoeck et al. are also outlined above. Neither Haralambopoulos nor Hoeck et al. teach human growth hormone as an active agent.

Marin teaches human growth hormone (hGH) can be used in combination with a cortisol synthesis inhibitor in a pharmaceutical composition. Marin discloses hGH formulations may be lyophilized in order to obtain a dry powder (col. 5 lines 27-28). Further, compositions which comprise hGH and saccharose are also disclosed (col. 5 lines 30-32). Marin also discloses the hGH compositions can be formulated as transdermal patches (col. 5 lines 40-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising hGH and saccharose into the transdermal patch of Haralambopoulos in view of Hoeck et al. because Marin teaches hGH formulations may be lyophilized to obtain a dry powder and formulated into a transdermal patch and Haralambopoulos in view of Hoeck et al. teach powdered bioactive substances can be spread uniformly as a thin layer on an non-adhesive polymeric layer of a matrix type transdermal patch (claims 27, 29, 32-34).

In their remarks, Applicants have amended instant claim 22 to include the limitation of a non-adhesive liner. Applicants' amendments and arguments are deemed to be sufficient in overcoming the use of the Haralambopoulos reference as a 102(b) rejection. However, the instant claims are believed to be unpatentable over Haralambopoulos in view of Hoeck et al., as noted in the instant 103(a) rejections.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-26, 29-36, 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 18-19 of copending Application No. 11327016. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the '016 claims are both drawn to a printed patch comprising a dried pharmaceutical composition comprising a polypeptide. Additionally, both the instant claims and the '016 claims also recite further elements such as stabilizers, i.e. carbohydrates, amino acids, polymers, and disaccharides that can be added and/or incorporated into the dried pharmaceutical composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 16, 2007

M. Monshi
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER